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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,627	04/17/2001	Robert A. Scott	6514-11-BHJ	7296

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EXAMINER

SHEIKH, HUMERA N

ART UNIT PAPER NUMBER

1615

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/836,627	Applicant(s) SCOTT ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 24, 25 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 24, 25 and 29-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RP

DETAILED ACTION

Status of the Application

Receipt of the request for extension of time (2 months-granted) and Applicant's Arguments/Remarks, both filed 02/10/05 is acknowledged.

Claims 1-21, 24, 25 and 29-33 are pending. No amendments to the claims have been made. Claims 1-21, 24, 25 and 29-33 remain rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7-10, 13-21, 24, 25 and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatano *et al.* (EP 0754 452 A2).

The instant invention is drawn to a drug delivery composition consisting essentially of a HPMC capsule provided with a single aqueous coating for delivering drug in the small intestine or colon.

Hatano *et al.* teach a coated capsule containing an acidic substance, a polymer film and an enteric coating, for medicament delivery to any site between the upper part of the small intestine and the lower part of the large intestine in the digestive tract (see pg. 3, lines 7-10). Hatano *et al.* teach that the enteric coating film protects the pharmaceutical preparation in the stomach and dissolves in the upper part of the small intestine, allowing the digestive juices to gradually penetrate and dissolve the acidic substance in the hard capsule (pg. 3, lines 11-19). According to Hatano *et al.*, the pharmaceutical agents in the capsule can be selectively released at any desired site between the jejunum and the rectum and any type of capsule can be used in the invention, including HPMC capsules (pg. 4, lines 6-20). Hatano *et al.* teach that the enteric polymer used for the enteric coating film must be soluble in a pH higher than 5 and includes a cellulose derivative, an acrylic polymer, a maleic copolymer, a polyvinyl derivative, shellac and the like among the polymers used for the enteric coating (pg. 4, lines 46-49). Among the exemplary polymers, Hatano *et al.* includes HPMC, methyl acrylate-acrylic acid copolymer, methyl acrylate-methacrylic acid copolymer and PVAP (pg. 4, lines 50-58 and pg. 5, lines 1-9). The Examiner, for the purpose of the invention, considers cellulose ester, which is mentioned in claims 15 of the present application as a component of the coating, as a cellulose derivative.

Hatano *et al.* teach that the amount of the enteric coating film is from 10-400% by weight based on the weight of the hard capsule (pg. 5, lines 41-46), and that the medicament in the capsule is not limited as long as it is orally administrable (pg. 8, lines 3-9). Hatano *et al.* teach that preferable solvents for the coating solution are water and alcohol (pg. 9, lines 8-19). Additionally, Hatano *et al.* teach that a sealing means can be provided around a joint of a body and a cap of the hard capsule and explains that the sealing agent can be any substance able to make the capsule's surface smooth at the joint, such as a water-soluble or insoluble polymer, a low pH-soluble or enteric polymer, a saccharide or the like (pg. 9, lines 23-55).

Thus, Hatano *et al.* provide a HPMC capsule provided with an enteric coating for delivering a drug in the small intestine or colon. Although Hatano *et al.* contemplates a capsule coated with multiple coatings, the reference teaches that only one enteric coating, which is soluble in an aqueous medium at pH higher than 5, is applied to the capsule.

Claims 6, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatano *et al.* (EP 0754 452 A2) as applied to claims 1-5, 7-10, 13-21, 24, 25 and 29-33 above and further in view of Watts (WO 95/35100).

The teachings of Hatano *et al.* are delineated above. Hatano *et al.* do not teach the inclusion of a redox-sensitive material in the coating of the HPMC capsule and do not teach cellulose acetate trimellitate (CAT).

Watts discloses a drug delivery composition for delivering a drug to the colonic region, comprising a coated starch capsule containing the drug (see pg. 3, lines 25-29). Watt teaches

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that the coating may be pH-sensitive, redox-sensitive or sensitive to the particular enzymes or bacteria, so that the capsules do not release the drug until it is in the colon (pg. 5, lines 9-14).

Watts teaches that preferred coating materials are those which dissolve at a pH of 5 or above, including CAT, HPMC, PVAP, shellac and cellulose esters, and that especially preferred materials are methylmethacrylates or copolymers of methacrylic acid and methylmethacrylate (pg. 5, lines 20-30 and pg. 6, lines 1-22). Watts explains that, because of the high presence of microbial anaerobic organisms providing reducing conditions in the colonic region, the coating may comprise a redox-sensitive material, such as azopolymers, which are broken down enzymatically, or disulphide polymers (pg. 6, lines 24-30 and p. 7, lines 1-2). It is the position of the Examiner that one of ordinary skill in the art would determine the optimal amount of the coating according to the size of the capsule by routine experimentation.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the drug delivery system disclosed by Hatano *et al.* by including a redox-sensitive material in the coating of the HPMC capsule, as taught by Watts, and applying the suitable coating in the optimal range determined by routine experimentation, before or after filing the capsule with the caplet, to ensure a complete disintegration of the coating in the small intestine or the colon and prevent drug leaking in the stomach. The expected result would be an improved drug delivery composition. Based on the teachings of Hatano *et al.*, that any kind of medicament can be delivered to any desired site between the upper part of the small intestine and the lower part of the large intestine in the digestive tract, by controlling the amount and the kind of polymers used for the coating of the HPMC capsule, one of ordinary skill in the art would have a reasonable expectation that the HPMC capsule device of the present application

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would successfully deliver drugs to the small intestine or colon. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art.

Response to Arguments

Applicant's arguments filed 02/10/05 have been fully considered but they are not persuasive.

Firstly, Applicant argued regarding the 35 U.S.C. §103(a) rejection of claims 1-5, 7-10, 13-21, 24, 25 and 29-33 over Hatano et al. (EPO 0 754 452 A2) stating, "Hatano teaches a coated capsule comprising 3 components: i.e. a hard capsule, a polymer film soluble at low pH and an enteric coating film. The descriptions and all of the examples of Hatano clearly show that two separate coatings on the hard capsule are required. Nothing in Hatano teaches how to create a useable product with a single aqueous coating. In contrast, the current claims are specifically limited to a single aqueous coating."

These arguments have been fully considered, but were not found to be persuasive. Applicants claim recitation of a 'single aqueous coating' in claim 1 does not limit the number of layers that may additionally be present in the formulation. The phrase 'consisting of' to reference the layers is not being claimed.

Secondly, Applicant argued regarding the 35 U.S.C. §103(a) rejection of claims 6, 11 and 12 over Hatano et al. (EPO 0 754 452 A2) in view of Watts (WO 95/35100) stating, "Watts teaches the use of an injection molded starch capsule. Watts does not teach either (i) an HPMC capsule or (ii) coating an HPMC capsule with a single aqueous coating. None of the examples of

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Watts describe a capsule with a single coating. The combination of Hatano and Watts is also incorrect since Watts is limited to injection molded starch capsules. The direct application of an enteric and colonic functional polymer coating onto an HPMC capsule substrate is not obvious.”

These arguments have been fully considered, but were not found to be persuasive. The teachings of Hatano *et al.* are delineated above. Hatano *et al.* do not explicitly teach the inclusion of a redox-sensitive material in the coating of the HPMC capsule and do not teach cellulose acetate trimellitate (CAT). The secondary reference of Watts was relied upon to remedy this deficiency of Hatano *et al.* by his teaching demonstrating that it is well known in the art to employ redox-sensitive materials and coating materials, particularly cellulose acetate trimellitate (CAT) in capsule formulations. Moreover, it is noted that Hatano *et al.* initially teach a HPMC capsule that provides release of drug into the intestines and they explicitly teach that HPMC capsules are preferred (page 4, lines 17-20). Applicant’s argument that an ‘HPMC capsule with a single aqueous coating is not taught’ is further not persuasive, since as pointed out above, Applicants’ claim recitation of a ‘single aqueous coating’ in claim 1 does not limit the number of layers that may additionally be present in the formulation. The instant claims, as currently recited permit the presence of additional layers. Furthermore, the recitation of ‘consisting essentially of’ makes reference to the HPMC capsule and not to the coating layers. Therefore, based on the teachings of Hatano and Watts, the instant invention is rendered *prima facie* obvious to one of ordinary skill in the art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh *H.N.S.*

Patent Examiner

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May 16, 2005

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